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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,139	08/10/2001	Marianne Langston	GJE-136D1	6929

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/19/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,139

Applicant(s)

LANGSTON ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants petition of revival has been granted. The response filed by applicants dated Aug. 18, 2003 have been entered and considered carefully. Claims 1-8 are pending.

Applicants requested the acknowledgement of the receiving of the priority documents. It is noted that the parent application claimed benefit of provisional application 60/021,135 which was not of record to have foreign priority benefit. It is requested that records of filing and claiming such benefit under 35 USC 119 be made of record for this application.

The record of this application is not clear as to the "common" ownership as described in the response. Submission of record is required.

2. The rejection of claims 1-8 over Shaflee in view of Barry or Miller, Shaflee in view of Barry or Miller further in view of Rometsch, over Shaflee in view of Barry or Miller further over Rometsch and Jacques supplemented with Harris are maintained for reason of record.

Applicant's argument is based on racemization of the "two chiral" center. Please note that racemization involving two chiral center was disclosed by Miller see col. 2, R,S-HPCA.DAA etc. which are material with two chiral center which are racemized for additional S-enantiomer (see col. 1 line 65-66). Criticality in racemization into "four" enantiomers, thus, is not because of the "two" chiral centers but the conditions employed to ensure all four enantiomers are formed simultaneously. Just because the prior art such as Rometsch did not *name* all four enantiomers, does not mean the racemization using the same acid would not give all four enantiomers. Such can only be obviated by *factual* comparison.

Applicants' attention is drawn to page 4 of the specification wherein the "nature" process of a single isomer will racemise into four enantiomer was described at lines 5-11 then the instant process of five steps was described wherein the process was the same as those scheme of page 2 that a dl-threo methylphenidate was resolved into single isomers d or l then the l-isomer was racemized. Applicants provided no factual evidence to demonstrate that the **very same** compound of the prior art upon recamization would not give four enantiomer which is the nature outcome for such compound.

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3. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for reason of record.

The specification lacks sufficient description to the instant claims because it is noted that the first step of the instantly claimed process is to resolve *dl-threo*-methylphenidate by the procedure described in the example of PCT/GB97/00185 which is now made of record. Please note that incorporation by reference of essential material is limited to US patent only. Proper incorporation of such material to the specification must be made. The incorporation of material as now amended in the specification has been entered.

The material made by the example of PCT/GB97/00185 is the ditoluoyl-D-tartrate salt of *l-threo*-methylphenidate and ditoluoyl-D-tartrate salt of *d-threo*-methylphenidate. No descriptive support can be found as to how such salt is racemized (see p.2 scheme 1) nor was there any descriptive support as to how the two ditoluoyl-D-tartrate salt can be embraced by scheme 1 of the instant specification, or the claimed process.

Further, it is irrelevant arguments presented by applicants as to criticality of how many chiral center when "what" is being made, is it methylphenidate or methylphenidate ditoluoyl-D-tartrate; or "what" is being racemized, is it methylphenidate or methylphenidate ditoluoyl-D-tartrate; were not sufficiently disclosed in the specification.

Based on the disclosure of pages 2-4 the claimed process as delineated in the scheme of page 2 does not required any criticality of how the two chiral center differ from the two chiral center of the prior art compound (please note Rometsch disclosed the same compound, thus, one skilled in the art would know there are the same two chiral center). Applicants provided no factual evidence to demonstrate that the **very same** compound of the prior art upon racemization would not give four enantiomer which is the nature outcome for such compound.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang
Dec. 16, 2003


Celia Chang
Primary Examiner
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